JAN 2 8 2002

K013667

510(K) SUMMARY

SUBMITTER IDENTIFICATION

Applicant's Name and Street Address: IS^2 Research Inc.
20 Gurdwara Road, Units 3 - 6,
Nepean, Ontario, Canada
K2E 8B3

Contact Person: Victor Woodburn, Manager Quality and Regulatory

Telephone and Fax Numbers of Contact Person: T - (613) 228-8755, F - (613) 228-8228

Address of Manufacturing Site: same as Applicant's address above

Date of Submission: October 2001

DEVICE NAME

Device Name (common): Gamma Camera
Proprietary Name: BCC
Classification Name: Planar Scintillation Camera Imaging

INTRODUCTION

This 510(k) Premarket Notification has been prepared to demonstrate that the BCC, manufactured by IS^2 Research Inc., is substantially equivalent to the NuCamma Bi90 camera, which has previously, underwent the 510(k) premarket notification process. The BCC nuclear imaging system has two rectangular fields of view detector heads.

INTENDED USE

The intended use of BCC is to detect the location and distribution of gamma ray emitting radionuclides in the body and store the data for analysis. This device includes accessories such as signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The intended use of the BCC is a reduced range of studies of NuCamma Bi90 can perform the identical studies to the BCC. The detector heads are identical in hardware and software. The gantry of the BCC is optimized for clinical study of the breast and does not have the range of automatic motions of the NuCamma Bi90

The BCC has been deemed safe and effective and is certified to the same electrical safety standards as the predicate device by a third party organization prior to use on patients. A matrix was constructed comparing the features and intended use of the BCC with the predicate device. We conclude that the BCC is substantially equivalent to the predicate device and that no new safety or effectiveness concerns are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2002

Mr. Victor Woodburn
Manager, Quality and Regulatory
IS^2 Research Inc.
20 Gurdwara Road, Bays 3-6
Nepean, Ontario, Canada
K2E 8B3

Re: K013667
Trade/Device Name: Breast Cancer Camera (BCC)
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: 90 KPS
Dated: October 31, 2001
Received: November 6, 2001

Dear Mr. Woodburn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013667

Device Name: BREAST CANCER CAMERA

Indications For Use:

THE BREAST CANCER CAMERA IS INTENDED TO USE TO DETECT AND IMAGE THE DISTRIBUTION OF THE GAMMA EMITTING RADIONUCLIDE IN THE PATIENT'S BREAST AND SURROUNDING AREA AND TO STORE THE IMAGES WHEN THE RADIONUCLIDE IS ADMINISTERED INTO THE PATIENT'S BODY.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013667

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)